REMARKS

Claims 1-7, 14-21, 29-45, 54-59 are pending for examination with claims 1, 29, 37 and 54 being independent claims. No new matter has been added.

Applicants confirm the cancellation of claims 46-53 as indicated in the Office Action and as discussed during a telephone conference with the Examiner on April 30, 2003.

Rejections Under 35 U.S.C. §103

Claims 1-7, 14-17, 20, 29-35, 37-44, 54 and 58

Claims 1-7, 14-17, 20, 29-35, 37-44, 54 and 58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser et al. (U.S. Patent No. 5,766,246). Applicants respectfully traverse this rejection.

Independent claims 1, 29, 37 and 54 are each directed to an implantable prosthesis including, *inter alia*, a layer of repair fabric and a barrier layer configured to inhibit the formation of adhesions between at least a portion of a surface of the repair fabric and adjacent tissue and organs. The layer of repair fabric has an outer peripheral edge or an outer margin with an outer peripheral edge.

Claim 1 recites that the prosthesis also includes a peripheral barrier that inhibits the formation of adhesions with adjacent tissue and organs.

Claims 29 and 54 recite that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

Claim 37 recites that the outer margin has been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs.

Mulhauser discloses an implantable prosthesis including a layer of repair fabric (12) and a semi-rigid frame or ring (14) for maintaining the prosthesis in a predetermined shape. In one embodiment shown in Figs. 2a-2b, the ring (14) extends about the periphery of the repair fabric. In another embodiment shown in Figs. 4a-4b, the prosthesis includes a barrier layer (36) to isolate the fabric (34) from sensitive tissues and organs. (Col. 5, lines 24-25). As illustrated, the

barrier layer extends beyond the ring to cover portions of the fabric also extending beyond the ring.

The Examiner contends that the ring (14) forms a peripheral barrier having an outer margin that has been melted and resolidified. The Examiner also contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Figs. 2a-2b prosthesis by adding the barrier layer (36) of the Figs. 4a-4b prosthesis to prevent undesirable adhesions with nearby organs, thereby rendering the claims obvious. Applicants respectfully disagree.

Without acceding to the propriety of the modification suggested by the Examiner, the resulting prosthesis does not include either a peripheral barrier that inhibits the formation of adhesions, as recited in claim 1, or an outer peripheral edge adapted to inhibit the formation of adhesions thereto, as recited in claims 29, 37 and 54. Mulhauser does not teach or suggest that the ring (14) has any type of adhesion inhibiting properties. Mulhauser only indicates that the frame (14) may be formed from a polypropylene material, a silicone material or other semi-rigid materials which are stiffer than the fabric yet significantly pliable to be rolled-up.

The ring (14) is not inherently resistant to adhesions simply based on the type of material used to form the ring; for example, the repair fabric is preferably formed of a sheet of knitted polypropylene monofilament mesh fabric, such as Marlex®, which promotes tissue ingrowth into and around the mesh structure. (Col. 4, lines 35-37). Rather, various factors such as surface texture and pore size of the material of the frame affect its ability to inhibit adhesions. Thus, one of ordinary skill in the art would not recognize the frame as necessarily inhibiting the formation of adhesions.

Alternatively, Mulhauser indicates that the ring (14) may be formed by hot or cold forming a ring-shaped depression in the mesh sheet. However, "hot or cold forming" does not necessarily result in a structure that inhibits or is resistant to the formation of adhesions. Even when assuming, for the sake of argument only, that hot forming involves some degree of melting and resolidifying of the outer margin, it does not follow that the *entire* thickness of the outer peripheral edge would be adapted to inhibit the formation of adhesions thereto. Rather, the degree of melt would vary depending on a number of factors including die design, applied pressure, dwell time, temperature (heated die process) and frequency (sonic weld process). Additionally, it is unclear as to where the ring-shaped depression would even be formed (i.e.,

at the outer peripheral edge or spaced inward from the peripheral edge) on the fabric layer. Thus, one of ordinary skill in the art would recognize that hot or cold forming a ring-shaped depression does not necessarily result in the entire thickness of the outer peripheral edge being adapted to inhibit or be resistant to adhesion formation.

In view of the forgoing, the rejection of claims 1, 29, 37 and 54 as being unpatentable over Mulhauser under §103 is improper and should be withdrawn. Claims 2-7, 14-17 and 20, claims 30-35, claims 38-44 and claim 58 respectively depend from claims 1, 29, 37 and 54 and are patentable for at least the same reasons.

Claims 18, 19 and 45

Dependent claims 18, 19 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser as applied to claims 1, 16, 37 and 44 above, and in further view of Sharber et al. (U.S. Patent No. 6,075,180). Applicants respectfully traverse these rejections.

Without acceding to the propriety of these rejections advanced by the Examiner, claims 18 and 19 and claim 45 respectively depend from independent claims 1 and 37 and are patentable for at least the same reasons set forth above.

Claims 21, 36, 55-57 and 59

Dependent claims 21, 36, 55-57 and 59 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser as applied to claims 1, 20, 29, 35, 54 and 58 above, and in further view of Gianturco (U.S. Patent No. 5,258,000). Applicants respectfully traverse these rejections.

Without acceding to the propriety of these rejections advanced by the Examiner, claim 21, claim 36, and claims 55-57 and 59 respectively depend from independent claims 1, 29 and 54 and are patentable for at least the same reasons set forth above.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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Docket No. D00188.70125.US
Date: August 5, 2003
x08/06/03